(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 22 September 2005 (22.09.2005)

PCT

(10) International Publication Number WO 2005/087201 A1

- (51) International Patent Classification⁷: A61K 9/16, 38/27
- (21) International Application Number:

PCT/NL2005/000205

- (22) International Filing Date: 18 March 2005 (18.03.2005)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:

04075884.9 18 March 2004 (18.03.2004) E

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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

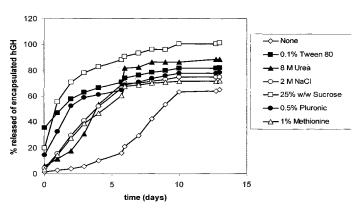
Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

[Continued on next page]

(54) Title: HYDROGEL MICROSPHERES WITH IMPROVED RELEASE PROFILE

In vitro release of hGH with and without excipients (size exclusion chromatography)



(57) Abstract: The invention provides an emulsion-based method for the preparation of controlled release microspheres for the delivery of active compounds. The method comprises the preparation of an emulsion comprising an aqueous dispersed phase which comprises a polymer capable of forming a hydrogel, a bioactive protein, and water, and which is substantially free from insoluble aggregates of the bioactive protein. Subsequently, the polymer physically or chemically crosslinked to form a hydrogel. The invention further provides active protein-loaded hydrogel microspheres which are prepared by the process, and which are substantially free from insoluble aggregates of the active protein. The microspheres exhibit controlled release, with release profiles which are considerably improved over those of previously known hydrogel microspheres. The microspheres may be used to deliver therapeutic or diagnostic proteins by injection.



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